No. 43252-8-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN,
Appellants,

v.

CITY OF PORT ANGELES, and CITY OF FORKS,
Respondents.

AMICI CURIAE BRIEF OF OWOC! AND WASW

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I. IDENTITY AND INTEREST OF AMICI CURIAE

The Amici Curiae are Our Water–Our Choice! ("OWOC!"), a Washington State political committee, and Washington Action for Safe Water ("WASW"), a Washington State non-profit corporation. The interests of each group are set forth in Appendix B hereto.

II. INTRODUCTION

OWOC! and WASW have both worked for many years on issues under review in the instant case. In reviewing the trial court's decisions on the motions to dismiss, this Court can consider alleged, judicially-noticed, possible, and hypothetical facts. This brief provides additional relevant facts that either can be judicially-noticed or that can be considered possible or hypothetical. These facts and the arguments that OWOC! and WASW make in reliance on facts will be of substantial assistance to this Court.

OWOC! and WASW request that this Court, at a minimum, reach the decision that, under the facts, City fluoridation products are drugs pursuant to 21 U.S.C. 321(g)(1)(B). It is public policy in order to protect consumers to hold drugs to higher standards than are required generally for water additives. These higher standards are justified because of the higher risks presented by drugs, including fluoridation products. The Centers for Disease Control and Prevention ("CDC") found that 41% of children in the U.S. were getting dental fluorosis from too much fluoride ingestion. ACP 238. Photographs of dental fluorosis are provided on page B-13 of the Third Declaration of Eloise Kailin filed in the Supreme Court with the Statement of Grounds for Direct Review.

III. STATEMENT OF THE CASE

OWOC! and WASW adopt by reference the Statement of the Case in the Brief of Appellants at 6 to 8 and adopt by reference the Response to Cross/Appellants' Statement of the Case in the Reply Brief of Appellants/Cross Respondents ("Citizens' Reply") at 10 to 18.

IV. ARGUMENT

A. Standard Of Review

1. Adoption by reference of Appellants' argument regarding standard of review

OWOC! and WASW adopt by reference the Standard of Review argument in the Brief of Appellants at 9 to 11 and adopt by reference the Standard of Review argument in the Citizens' Reply at 18 to 22.

2. This Court may consider possible and hypothetical facts not included in the record

In reviewing a CR 12(b)(6) and CR 12(c) motion, this Court may consider possible and hypothetical facts not included in the record. *See* Brief of Appellants 9-10.

B. OWOC! And WASW Request That This Court Take Judicial Notice Of Adjudicative Facts

OWOC! and WASW attach as Appendix A to this Brief the Declaration of Gerald Steel and request that this Court take judicial notice of the adjudicative facts in this Declaration. Judicial notice of adjudicative facts may be taken at any stage of proceedings. ER 201(f). Judicially noticed facts must be ones not subject to reasonable dispute and include facts capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. ER 201(b). A court shall take judicial notice if

requested. ER 201(d).

Judicial notice should be taken of the following facts included in the Declaration of Gerald Steel ("Steel Dec."). References to Appendix pages in this section are references to the Appendix to the Declaration of Gerald Steel.

- Appendix A-1 is a copy (without appendices) of a letter mailed to Secretary Kathleen G. Sebelius of U.S. Health and Human Services ("HHS") on November 26, 2011 that was delivered on November 28, 2011. *See* Steel Dec. Para. 3-5.
- HHS did not deliver by February 6, 2012 to Gerald Steel or Eloise Kailin a written statement from HHS that identifies the classification of water fluoridation products and the component of FDA that will regulate these products. *See* Steel Dec. Para. 7 and 15 and Appendix A-18 to A-19 Para. 2.
- Appendix A-6 is a copy (without appendices) of a letter mailed to Secretary Kathleen G. Sebelius of HHS on February 6, 2012 that was delivered on February 10, 2012. *See* Steel Dec. Para. 8-10.
- HHS did not deliver to Gerald Steel or Eloise Kailin a request for (or notice of) modification pursuant to 21 U.S.C. 360bbb-2(c) and neither Gerald Steel nor Eloise Kailin have provided written consent to any modification from the final determination by the Secretary of HHS that fluoridation products are drugs and prescription drugs regulated by CDER. *See* Steel Dec. Para. 11 and 15 and Appendix A-18 to A-19 Para. 3.
- Appendix A-9 to A-13 is a copy of the first 5 pages of a letter dated August 3, 2012 mailed to Region 10 Administrator of U.S. EPA, Dennis J. McLerran.

- Appendix A-14 is a copy of the letter from Region 10 of U.S. EPA in response to the said August 3, 2012 letter. *See* Steel Dec. Para. 13.

- Appendix A-17 is a copy of a page from the presentation given by Bill Osmunson DDS MPH to the state Board of Pharmacy that frames the requests that are answered in the Board's decision provided in Amended Appellants' Clerk's Papers ("ACP") 46. *See* Steel Dec. Para. 14 and Appendix A-15 to A-16 Para. 5. A copy of ACP 46 is provided in Appendix C to this Brief.

These documents are appropriate for judicial notice because the facts surrounding their existence are not subject to reasonable dispute and are capable of accurate and ready determination by resort to agency records whose accuracy cannot reasonably be questioned. *See* ER 201(b).

C. This Court May Take Judicial Notice Of The Facts In The Documents In Appendix A Hereto Or This Court May Consider The Facts In These Documents Possible Or Hypothetical Facts

This Court may take judicial notice of the facts in the documents in Appendix A hereto, or this Court may consider the facts in these documents possible or hypothetical facts. In either case, these facts are to be taken in the light most favorable to Appellants when reviewing a motion to dismiss under CR 12(b)(6) and CR 12(c). *See* Brief of Appellants at 9-10.

D. Under The Facts In Appendix A Hereto, The Secretary Of HHS, As A Matter Of Law, Has Made A Final Determination That Fluoridation Products Are Federal Drugs And Federal Prescription Drugs

1. 21 U.S.C. 360bbb-2 allows a person to get a final determination by the Secretary of HHS regarding the classification of a product and regarding the component of FDA that will regulate the product

21 U.S.C. 360bbb-2 allows a person to get a final determination by the Secretary of HHS ("Secretary") regarding the classification of a product and regarding the component of FDA that will regulate the product. This federal statute adopted by congress and signed by the president is provided in the Declaration of Gerald Steel, Appendix A-4 to A-5.

Under subsection (a) of this statute a person may make a submittal to the Secretary with a request for the Secretary to determine the classification of a product and the component of FDA that will regulate it. 21 U.S.C. 360bbb-2(a); Steel Dec. Appendix A-4. In submitting the request, "the person shall recommend a classification for the product, or a component to regulate the product." *Id.* A letter was submitted to the Secretary for a determination with a recommendation that fluoridation products be classified as drugs and prescription drugs to be regulated by CDER. Steel Dec. Appendix A-1.

Under subsection (b) of this statute, the Secretary is required within 60 days of delivery of the request to provide the person a written statement that identifies the classification for the product, and the component of FDA that will regulate the product. 21 U.S.C. 360bbb-2(b); Steel Dec. Appendix A-4. The Declaration of Gerald Steel establishes that the Secretary did not provide such a written statement within the said 60 days. *See* Steel Dec. Para.

7 and 15 and Appendix A-18 to A-19 Para. 2.

Under subsection (c) of this statute, when the Secretary does not provide the written statement identified in subsection (b) within the 60-day period, then as a matter of law, the recommendation made by the person pursuant to subsection (a) "shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product." 21 U.S.C. 360bbb-2(c); Steel Dec. Appendix A-4. This final determination may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence. *Id.*

Pursuant to the judicially-noticed facts (or possible or hypothetical facts) in the Declaration of Gerald Steel, a letter was sent to the Secretary on February 6, 2012 (70 days after delivery of the initial request to the Secretary) explaining that because the required written statement had not been timely-received, Dr Kailin's recommendation that fluoridation products are both drugs and prescription drugs regulated by CDER is considered to be the final determination by the Secretary pursuant to 21 U.S.C. 360bbb-2(c). Steel Dec. Appendix A-6. No written consent was given by Eloise Kailin or Gerald Steel to allow this final determination to be modified. *See* Steel Dec. Para. 11 and 15 and Appendix A-18 to A-19 Para. 3. No notice of modification for public health reasons based on scientific evidence pursuant to 21 U.S.C. 360bbb-2(c) was provided by the Secretary. *Id.*

2. The Appellants (collectively "Citizens") have alleged as a fact that the FDA has determined that fluoridation products are federal drugs and prescription drugs

The first argument of Citizens is that fluoridation products are intended for use in the prevention of disease in man and therefore pursuant to the FFDCA, at 21 U.S.C. 321(g)(1)(B), they are federal drugs. Brief of Appellants at 16. The first argument of Respondents ("Cities") is that "there is no set of facts that Petitioners could prove showing that the FDA actually does classify the . . . Cities' bulk fluoridation additives as federal legend [prescription] drugs." Brief of Respondents ("City Br.") at 21. Citizens request that this Court find that the FFDCA designates, by definition, certain substances as drugs whether or not the FDA has acted. Citizens' Reply at 14.

Citizens, however, have alleged as a fact that the FDA has determined that fluoridation products are federal drugs and prescription drugs. *See* Citizens' Reply at 24-25. Citizens correctly argues that in review of a CR 12(b)(6) or CR 12(c) motion, the facts alleged in the complaint, as well as possible or hypothetical facts, are to be taken in the light most favorable to Citizens. Brief of Appellants at 9-10. The judicially-noticed or possible or hypothetical facts in the Declaration of Gerald Steel, taken in the light most favorable to Citizens, demonstrate that HHS, the agency that includes FDA, as a matter of law, has now made a final determination that fluoridation products are federal drugs and federal prescription drugs. These new facts support Citizens' factual allegation that fluoridation products are federal drugs and federal prescription drugs.

E. There Is No Merit To The Cities' Mantra That Citizens' Claim, That Fluoridation Additives Have Been Designated As Prescription Drugs Under Federal Law, Is Frivolous

In the Reply Brief of Respondents/Cross Appellants City of Port Angeles and City of Forks ("City Reply"), the Cities use the word frivolous thirteen times apparently believing that the more often they use the word, the more likely this Court will rule in their favor. The Cities state:

> there is no law or fact supporting Petitioners' frivolous claim that fluoridated drinking water or fluoridation additives . . . have been designated as prescription drugs under federal law

City Reply at 12.

The facts and law are well-established that fluoridation additives are designated as prescription drugs by federal law. The state Board of Health has ruled that it is "self evident that the purpose of water fluoridation is to help prevent tooth decay." ACP 124. The NSF who certifies fluoridation products and who wrote ANSI/NSF Standard 60 (which is relied upon in WAC 246-290-220(3)) states "Fluoride is added to water for the public health benefit of preventing . . tooth decay." ACP 122. The CDC states tooth decay is a disease. ACP 346-47. The FFDCA defines "drug" as including "articles intended for use in the . . . prevention of disease in man." 21 U.S.C. 321(g)(1); Brief of Appellants at A-20 to A-21. There is no other intent of fluoridation products except to prevent tooth decay. Read together, these facts and law establish that fluoridation additives are drugs. Federal drugs are either Over-The-Counter ("OTC") or prescription. It is undisputed that the Cities' bulk fluoridation products are not OTC drugs. See ACP 181-84; Brief of Appellants at 34. Therefore these drugs are federal prescription drugs.

When federal prescription drugs are compounded with water, the

compound (called fluoridated water) used with intent to prevent tooth decay remains a federal prescription drug unless it has OTC approval. *See* Brief of Appellants at 34-35. No one claims that these fluoridated waters have OTC approval. *See* ACP 381. Therefore, the Cities' fluoridated waters remain federal prescription drugs. Therefore, the Cities bulk fluoridation additives and fluoridated waters are federal prescription drugs under the laws and facts in the record. OWOC! and WASW request that this Court explicitly make this finding. Appellants' Issue Nos. 1 and 4.

F. This Court Should Exercise Its Jurisdiction To Determine That City Fluoridation Products and Fluoridated Water Are Federal Drugs And Federal Prescription Drugs After Considering The Doctrine of Primary Jurisdiction

1. The Cities have not met their burden to show that the standards to apply the doctrine of primary jurisdiction are met

Fundamentally, Congress has designated drugs by definition by enacting 21 U.S.C. 321(g)(1). The HHS/FDA and the Courts have concurrent jurisdiction to apply this statute to the facts and determine if City fluoridation products and City fluoridation products compounded with waters (City fluoridated waters) are drugs. *See* WASH. CONST. art. IV, Sec. 6 for superior court original jurisdiction; *see also Biotics Research Corporation v. Heckler*, 710 F.2d 1375, 1376-77 (9th Cir. 1982) ("courts and the FDA share concurrent jurisdiction" but "FDA has primary jurisdiction"regarding certain federal drug statutes). The Cities argue that Citizens were required by law (by the doctrine of primary jurisdiction) to first get a determination by the FDA. City Reply at 9.

The application of the doctrine of primary jurisdiction is not

mandatory in any given case, but rather is within the sound discretion of the court. *Chaney v. Fetterly*, 100 Wn.App. 140, 149, 995 P.2d 1284 (2000, Div. II), *review denied*, 142 Wash.2d 1001, 11 P.3d 824 (2000). Because the superior court has original jurisdiction, exhaustion of administrative remedies is not required. *Id.* If the doctrine of primary jurisdiction were applied, the court would suspend the case pending referral to HHS/FDA for its view as to whether the City fluoridation products and City fluoridated waters are federal drugs and federal prescription drugs. *Id.* The court would normally retain the power to make the final decision. *Jaramillo v. Morris*, 50 Wn.App. 822, 828, 750 P.2d 1301 (1988), *review denied*, 110 W.2d 1040 (1988).

For the court to apply the doctrine of primary jurisdiction, the Cities must meet their burden to show:

> 1) The administrative agency has the authority to resolve the issues that would be referred to it by the court;
>
> 2) The agency has special competence over all of some part of the controversy which renders the agency better able than the court to resolve the issues; and,
>
> 3) The claim Before the court involves issues that fall within the scope of a pervasive regulatory scheme so that a danger exists that judicial action would conflict with the regulatory scheme.

Chaney at 150.

All three of these standards are not met and so referral to HHS/FDA is not warranted. The first standard is not met because the argument made by the Cities is not that City fluoridation products and fluoridated waters do not meet the definition for drugs in 21 U.S.C. 321(g)(1)(B), but rather that the EPA and not HHS/FDA exercises exclusive authority over fluoridation additives because of the Safe Drinking Water Act and a 1979 MOU. City Br.

at 16-18. The HHS/FDA does not have authority to resolve this jurisdictional issue between the agencies and so the first standard is not met.

Regarding the second standard, the facts are undisputed that fluoride is added to water for the public health benefit of preventing tooth decay, the purpose of water fluoridation is to help prevent tooth decay, and tooth decay is a disease. *Supra*, this brief at 8. There are no technical terms in 21 U.S.C. 321(g)(1)(B) that would require agency expertise to interpret and so the agency is no better able than the court to determine if the City fluoridation products and fluoridated waters are federal drugs under that statute. Interpretation of a statute is solely a question of law within the conventional competence of the court. *American Legion Post # 32 v. City of Walla Walla*, 116 Wn.2d 1, 5-6, 802 P.2d 784 (1991).

American Legion Post # 32 at 6 distinguishes the holding in that case (that primary jurisdiction should not be applied) from the holding in *Jaramillo v. Morris*, 50 Wn.App. 822, 828-29, 750 P.2d 1301 (1988), *review denied*, 110 W.2d 1040 (1988). In *Jaramillo*, the trial court was reversed when it refused to grant a request to reconsider its order on summary judgment when it was informed that the expert agency interpretation of a relevant technical medical term was inconsistent with the trial court's interpretation of that same term in its summary judgment order. *Jaramillo* at 825-33. In the instant case, there are no relevant technical terms that require agency interpretation. Therefore the second standard is not met.

It is undisputed that the City's bulk fluoridation products and fluoridated waters are not OTC drugs (*supra*, this brief at 8) and so if they are federal drugs, they are federal prescription drugs.

Regarding the third standard, there is no pervasive regulatory scheme that could be resolved by a single agency referral that would be put in danger by a judicial decision. The required judicial decision is a straight-forward application of the plain meaning of a statute to undisputed facts. Because all three standards are not met, the doctrine of primary jurisdiction should not be applied. This Court should determine if the City fluoridation products and City fluoridation products compounded with City waters (fluoridated waters) are federal drugs and federal prescription drugs under 21 U.S.C. 321(g)(1)(B).

2. Under the alleged, judicially-noticed, possible and hypothetical facts before this Court, the Secretary of HHS, as a matter of law, has made a final determination that the City fluoridation products are federal drugs and federal prescription drugs

As described above (*supra,* this brief at 6-7), the Secretary of HHS has considered whether fluoridation products are federal drugs and federal prescription drugs and, by law, has made a final determination that they are federal drugs and federal prescription drugs. There is no need for a further referral.

G. This Court Should Exercise Its Jurisdiction To Determine That City Fluoridation Products And Fluoridated Waters Are State Drugs, State Prescription Drugs, State Legend Drugs, And State Legend Drugs Under Chapter 69.41 RCW

If this Court finds that under the alleged, judicially-noticed, possible and hypothetical facts ("the facts"), the City fluoridation products are federal drugs and federal prescription drugs under 21 U.S.C. 321(g)(1)(B), then under the same facts, it should easily find that the City fluoridation products are state drugs, state prescription drugs and state legend drugs under RCW

18.64.011(11), RCW 69.04.009, RCW 69.41.010(9), and RCW 18.64.011(14). Whether, under the same facts, City fluoridation products are state legend drugs under Chapter 69.41 RCW is a closer question.

If this Court finds the City fluoridation products are federal drugs and federal prescription drugs under the facts, then the remaining argument of the Cities is that the City fluoridation products are not adequately listed in the 2009 Drug Facts Red Book. City Br. at 15. However, as Citizens point out, the real test is whether the City fluoridation products are legend drugs under chapter 69.41 RCW. Citizens' Issue No. 5. If these products are legend drugs under chapter 69.41 RCW, they are subject to seizure at the request of Citizens. ACP 260-61 Para. 12-14.

This is an issue where the state Board of Pharmacy is the relevant agency with special competence to make the initial determination whether fluoridation substances are legend drugs under chapter 69.41 RCW. This is an issue that was taken to state Board of Pharmacy in a petition from Dr. Bill Osmunson and WASW. Appendix A hereto is the Declaration of Gerald Steel which includes a copy of the Declaration of Bill Osmunson DDS MPH at Appendix A-15 to A-17. Said Appendix A-17 provides the requests that were made by Dr. Osmunson with his petition to the state Board of Pharmacy. Steel Dec. Appendix A-16 Para. 3-5. These requests apply explicitly and specifically to water fluoridation substances. *Id.* at Appendix A-17. Dr. Osmunson and WASW were asking for alternative rulings that "fluoridation substances" be designated as poison or regulated as legend drugs under chapter 69.41 RCW.

The ruling from the state Board of Pharmacy was given to the trial

court. ACP 46 (Appendix C hereto). In essence, the Board ruled that it would not designate "fluoridation substances" as poison because according to the state Board of Pharmacy, these substances are legend drugs "regulated under chapter 69.41 RCW." This ruling by the state Board of Pharmacy that fluoridation substances are regulated under chapter 69.41 RCW deserves great deference because the statute is ambiguous.

> where an agency is charged with the administration and enforcement of a statute, the agency's interpretation of the statute is accorded great weight in determining legislative intent when a statute is ambiguous.

City of Pasco v. Public Employment Relations Commission, 119 Wn.2d 504, 507, 833 P.2d 381 (1992). The statute is ambiguous as evidenced by the different plausible interpretations by the Cities and Citizens.

If, under the facts, this Court finds that the City fluoridation substances are state drugs under RCW 18.64.011(11), RCW 69.04.009, and RCW 69.41.010(9), and state prescription and legend drugs under RCW 18.64.011(14), and/or state legend drugs under Chapter 69.41 RCW, this Court should also find that the City fluoridation substances retain their drug status when they are compounded with City waters and distributed to consumers as fluoridated waters. These drugs retain their legend and prescription drug status because it is undisputed that the mixture of City fluoridation substances and City waters do not qualify as OTC drugs and these fluoridated waters are being delivered to consumers with intent to help prevent tooth decay.

H. The EPA Disagrees With The Cities' Claim That The EPA Regulates Fluoridation Additives And Disagrees With The Cities' Claim That The Authority Of EPA Prevents HHS/FDA From Exercising Their Drug Authority To Make A Finding That Fluoridation Products Are Drugs

The Cities argue that the EPA and not HHS/FDA exercises exclusive authority over fluoridation additives because of the Safe Drinking Water Act and a 1979 MOU. City Br. at 16-18. EPA has been asked a series of questions by OWOC! and WASW to help this Court evaluate the Cities' arguments and the EPA responses are provided in the Declaration of Gerald Steel Appendix A-9 to A-14.

EPA states:

> EPA does not provide recommendations for the addition of any substance (including fluoride) to drinking water for preventative health care purposes and is prohibited by SDWA from setting such requirements.

Steel Dec. Appendix A-10. EPA speaks of a new proposed recommendation by HHS of 0.7 mg/L for fluoride "for preventing tooth decay." Steel Dec. Appendix A-11. EPA states that in the state of Washington, decisions to fluoridate are made at the local level but when such decisions are made, the state Board of Health regulates the addition of fluoride to maintain a range of 0.8 to 1.2 ppm. *Id.* According to the EPA, WAC 246-290-220(3), the state regulation that requires additives for Washington public drinking water to comply with ANSI/NSF Standard 60, and WAC 246-290-460 that regulates the addition of fluoride when a decision to fluoridate is made at the local level, are both regulations "not related to the requirements of the Federal Safe Drinking Water Act ("SDWA") in Washington State. Steel Dec. Appendix A-12 to A-13.

In response to the questions by OWOC! and WASW about the authority of EPA to prevent HHS/FDA from exercising drug authority over fluoridation products (Steel Dec. Appendix A-9), the EPA responded:

> You ask if there is any law, regulation, or directive giving the EPA authority to prevent the Food and Drug Administration and/or Health and Human Services from exercising their drug authority to make a finding that fluoride products added to drinking water are drugs and if there is any law, regulation or directive giving EPA authority to reverse any FDA regulatory action resulting from such a finding. The answer to both of these questions is no. The EPA has no authority to intervene in the actions of these agencies.

Steel Dec. Appendix A-14.

The Cities' argument that EPA has exclusive jurisdiction over additives to drinking water is not true. *See* City Br. at 17-18. EPA does not have jurisdiction to regulate additives (including fluoride) for preventative health care purposes. *Supra*, this brief at 15. Also the Cities' argument that EPA has exclusive jurisdiction over public drinking water such that HHS/FDA cannot exercise its drug jurisdiction over fluoridation products and fluoridated waters is not true. *See* City Br. at 17-18. EPA has no authority to interfere with HHS and FDA exercising drug authority over preventative health care substances (including fluoride) added to public drinking water. *Supra*, this brief at 16.

I. If The City Bulk Fluoridation Products And Compounds Of These Products With Drinking Water Are Drugs, Then There Will Be Requirements To Comply With State And Federal Drug Laws And Regulations

If the City bulk fluoridation products and compounds of these products with City waters are state and federal drugs, there will be requirements to comply with state and federal drug laws as discussed in the Brief of Appellants at 31. Public drinking water will continue to be supplied but it will be up to the state and federal drug regulators as to whether fluoride can continue to added.

V. CONCLUSION

This Court should find that, under the facts, the City fluoridation products are drugs under federal and state law. Because it is undisputed that these products are not OTC drugs, this Court should find, under the facts, these products are prescription and legend drugs under federal and state regulations. This Court should defer to the state Board of Pharmacy and find that City fluoridation products are legend drugs under chapter 69.41 RCW. *See* ACP 46 provided in Appendix C to this brief. These fluoridation products remain prescription and legend drugs when they are added to municipal water supplies to make fluoridated water to help prevent tooth decay. *Supra*, this Brief at 8-9.

This Court should find that, under the facts, EPA does not provide recommendations for the addition of any substance (including fluoride) to drinking water for preventative health care purposes and is prohibited by the SDWA from setting such requirements. Appendix A hereto at A-10; Brief of Appellants at A-16 to A-19. This Court should also find, under the facts,

that the 1979 MOU (ACP 224-31) never applied to modify the drug authority of the FDA and that there is no law, regulation, or directive giving EPA authority to prevent the Food and Drug Administrative and/or Health and Human Services from exercising their drug authority to make a finding that fluoride products added to public drinking water are drugs (Appendix A hereto at A-14).

Because this Court can take judicial notice of the facts that water fluoridation is to help prevent tooth decay, that fluoride is added to water for the public health benefit of preventing tooth decay, and that tooth decay is a disease (*supra*, this brief at 8), this Court need not remand to the trial court for this Court to conclude that fluoridation products alone and when compounded with drinking water are federal drugs, federal prescription drugs, state drugs, state prescription drugs, state legend drugs, and legend drugs under chapter 69.41 RCW. This Court should reverse the motion to dismiss and remand to the trial court with direction to issue the warrants to seize in-place the City fluoridation products if the Cities are found in violation of WAC 246-899-040(1). See ACP at 260-61, Para. 11-14.

Dated this 4th day of December, 2012.

Respectfully submitted,

GERALD STEEL PE

By: _____
Gerald B. Steel, WSBA No. 31084
Attorneys for OWOC! and WASW

APPENDIX A

DECLARATION OF GERALD STEEL

No. 43252-8-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN, Appellants, v. CITY OF PORT ANGELES, and CITY OF FORKS, Respondents.	DECLARATION OF GERALD STEEL

COMES Now Gerald Steel, and declares as follows:

1) I am over the age of 21 and competent to testify. I make this declaration based on my own knowledge and belief.

2) I am the attorney for all the appellants in this case and for Our Water–Our Choice! ("OWOC!"), a Washington State political committee, and Washington Action for Safe Water ("WASW"), a Washington State non-profit corporation.

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG RD. NW
OLYMPIA WA 98502
Tel/fax (360) 867-1166

3) Appendix A-1 hereto is a true and correct copy of a letter from Eloise W. Kailin, M.D. regarding "Classification of Products per 21 U.S.C. 360bbb-2" that I mailed (certified with appendices) on behalf of OWOC! to Secretary Kathleen G. Sebelius of U.S. Health and Human Services ("HHS") on November 26, 2011.

4) Appendix A-2 hereto is a true and correct copy of the U.S. Postal Service Certified Mail Receipt with label number 70102780000365208164 that I received when I mailed the letter with appendices as described in Paragraph 3 above.

5) Appendix A-3 hereto is a true and correct copy of the USPS.com Track & Confirm Notice for label number 70102780000365208164 that shows this mail was delivered on November 28, 2011.

6) Appendix A-4 and A-5 hereto is a true and correct copy of 21 U.S.C. 360bbb-2 as downloaded on February 4, 2012.

7) By February 6, 2012, neither I nor Dr. Kailin had received a written statement from U.S. HHS that identifies the classification of water fluoridation products and the component of FDA that will regulate these products.

8) Appendix A-6 hereto is a true and correct copy of a letter from me regarding "Classification of Products per 21 U.S.C. 360bbb-2" that I mailed (certified with appendices) on behalf of OWOC! to Secretary Kathleen G. Sebelius of U.S. Health and Human Services ("HHS") on February 6, 2012.

9) Appendix A-7 hereto is a true and correct copy of the U.S. Postal Service Certified Mail Receipt with label number 70111570000279069957 that I received when I mailed the letter with appendices as described in Paragraph 8 above.

10) Appendix A-8 hereto is a true and correct copy of the USPS.com Track & Confirm Notice for label number 70111570000279069957 that shows this mail was delivered on February 10, 2012.

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11) Neither I nor Dr. Kailin have received a request or notice of modification from U.S. HHS pursuant to 21 U.S.C. 360bbb-2(c) and we have not provided written consent to any modification from the final determination by the Secretary of HHS that fluoridation products are drugs and prescription drugs regulated by CDER.

12) Appendix A-9 to A-13 hereto is a true and correct copy of the first 5 pages of a letter from me regarding a "Request for letter stating effect of EPA's authorities" that I mailed on behalf of OWOC! and WASA to the Region 10 Administrator of U.S. EPA, Dennis J. McLerran, on August 3, 2012.

13) Appendix A-14 hereto is a true and correct copy of the letter I received in response to the letter identified in Paragraph 12 above.

14) Appendix A-15 to A-17 is a true and correct copy of the Declaration of Bill Osmunson DDS MPH.

15) Appendix A-18 to A-19 is a true and correct copy of the Fourth Declaration of Eloise Kailin M.D.

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my knowledge and belief.

Signed the 4th day of December, 2012 at Olympia WA.

Gerald Steel

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November 25, 2011

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200 Independence Ave. S.W.
Washington D.C. 20201

Re: Classification of Products per 21 U.S.C. 360bbb-2

Dear Secretary Sebelius:

As you know, 21 U.S.C. 360bbb-2 allows a person to submit a request to the Secretary respecting the classification of a product and the component of the FDA that will regulate the product. I hereby request classification of fluoridation products as drugs and prescription drugs and I request that these products be regulated by CDER. According to NSF, International, fluoridation products that are tested and certified to NSF/ANSI Standard 60 are in three categories:

1. Fluorosilicic Acid (a.k.a. Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (a.k.a. Sodium Silicofluoride).
3. Sodium Fluoride

These fluoridation products are added to public water supplies for "preventing and reducing tooth decay." Appendix A hereto (from the NSF Fact Sheet on Fluoridation Chemicals). Because these substances are intended for use in the prevention of disease (dental caries, tooth decay) in man, they are anticaries drugs. (21 U.S.C. 321(g)(1)(B); *See* 21 CFR 355.3 ("Anticaries drug. A drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries)").) The FDA, through CDER, is responsible for ensuring that human drugs are safe and effective. (21 U.S.C. 393(b)(2)(B).) These fluoridation products do not meet OTC Conditions in 21 CFR Part 355 so they are not OTC drugs. Therefore they are federal prescription drugs. I attach an analysis detailing why these products are federal prescription drugs. (Appendix B hereto.) I also attach a listing of what I believe to be all manufacturers of fluoridation products used in the United States. (Appendix C hereto.) I request that these manufactures be sent a notice requiring them to register their fluoridation products pursuant to 21 CFR 207.25 or pursuant to other appropriate regulation.

Respectfully,

Eloise W. Kailin M.D.

Eloise W. Kailin, M.D.

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Sent To: Secretary Kathleen G Sebelius - U.S. HHS
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City, State, ZIP+4: Washington D.C. 20201

PS Form 3800, August 2006 — See Reverse for Instructions

A-2

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A-3

§ 360bbb-2. Classification of Products.

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter V. DRUGS AND DEVICES

Part E. General Provisions Relating to Drugs and Devices

Current through P.L. 111-290

§ 360bbb-2. Classification of Products

(a) **Request**

A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this chapter for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section **353 (g)** of this title or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) **Statement**

Not later than 60 days after the receipt of the request described in subsection (a) of this section, the Secretary shall determine the classification of the product under subsection (a) of this section, or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) **Inaction of Secretary**

If the Secretary does not provide the statement within the 60-day period described in subsection (b) of this section, the recommendation made by the person under subsection (a) of this section shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

A-4

Notes from the Office of Law Revision Counsel

Current through 2009-01-05

Source

(June 25, 1938, ch. 675, § 563, as added **Pub. L. 105-115**, title IV, § 416, Nov. 21, 1997, 111 Stat. 2378.)

Effective Date

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of **Pub. L. 105-115**, set out as an Effective Date of 1997 Amendment note under section **321** of this title.

A-5

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG ROAD NW
OLYMPIA, WA 98502
Tel/fax (360) 867-1166

February 6, 2012

Secretary Kathleen G. Sebelius
U.S. HHS
200 Independence Ave. S.W.
Washington D.C. 20201

Re: Classification of Products per 21 U.S.C. 360bbb-2

Dear Secretary Sebelius:

I am writing this letter on behalf of Dr. Eloise Kailin and Our Water-Our Choice! Pursuant to 21 U.S.C. 360bbb-2, Dr. Kailin on behalf of Our Water-Our Choice! submitted to you a letter request, dated November 25, 2011, requesting and recommending classification of fluoridation products as both drugs and prescription drugs regulated by CDER. Dr. Kailin's letter was received by you on November 28, 2011. Exhibit E 1 hereto. Donald Dobbs of CDER responded with a letter dated December 15, 2011. Exhibit E 2 hereto.

21 U.S.C. 360bbb-2(b) provides that not later than 60 days after the receipt of our request, you were required to provide Dr. Kailin with a written statement that identifies the classification of such fluoridation products and the component of FDA that will regulate the products. Exhibit E 3-4 hereto. Sixty days after November 28, 2011 is January 27, 2012. Dr. Kailin informs me that she was not timely-provided with your required statement.

21 U.S.C. 360bbb-2(c) provides that because the required statement was not timely-provided, Dr. Kailin's recommendation that fluoridation products are both drugs and prescription drugs regulated by CDER is considered to be the final determination by the Secretary. 21 U.S.C. 360bbb-2(c) further provides that this final determination may not be modified by the Secretary except with the written consent of Dr. Kailin (or Our Water-Our Choice!), or for public health reasons based on scientific evidence. Please confirm this determination.

I provide the Biography of Dr. Kailin in Exhibit E 5-10 hereto. For your information, I also provide in Exhibit E 11-15, a recent letter to CDER from Dr Richard Sauerheber that explains his concern that no federal agency has taken responsibility to determine whether fluoridation products are safe and effective and no agency accepts liability or responsibility for fluoridation.

Respectfully,

Gerald Steel, WSBA #31084
Attorney for Our Water-Our Choice!
and Dr. Kailin

Attachments: E 1-15
cc: FDA (addressed as requested
in said December 15, 2011 letter)

A-6

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A-7

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		Dispatched to Sort Facility	February 06, 2012, 5:15 pm	OLYMPIA, WA 98501	
		Acceptance	February 06, 2012, 12:09 pm	OLYMPIA, WA 98501	

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A-8

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG ROAD NW
OLYMPIA, WA 98502
Tel/fax (360) 867-1166

August 3, 2012

Dennis J. McLerran, Regional Administrator
U.S. EPA, Region 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

Re: Request for letter stating effect of EPA's authorities

Honorable Dennis McLerran,

I want to begin by thanking you for the attached April 7, 2011 and November 17, 2011 letter responses from your office. On page 1 of the said April letter, you state:

> Under the SDWA, EPA's role in drinking water regulations is to set standards that define the maximum allowable concentrations of contaminants in order to prevent adverse health effects. EPA does not provide recommendations for the addition of any substance (including fluoride) to drinking water for preventative health care purposes and is prohibited by SDWA from setting such requirements.

Page 1 of the said November letter states,

> WAC 246-290-220(3) and 246-290-460 are not related to the requirements of the Federal Safe Drinking Water Act in Washington State.

As you recall, WAC 246-290-220(3) requires additives for Washington public drinking water to comply with ANSI/NSF Standard 60. WAC 246-290-460 addresses fluoridation practices in Washington should a community choose to provide fluoridation.

I have some new requests and would appreciate a letter response from you regarding any EPA authority that would restrict FDA and HHS from exercising their drug authority over fluoridation products. I ask, does EPA have any law, regulation, or controlling directive giving EPA authority to prevent FDA and/or HHS from exercising their drug authority to make a finding that fluoridation products to be used in public drinking waters are drugs (articles intended for use in the treatment or prevention of disease per 21 U.S.C. 321(g)(1)(B))? If so, would you please identify any such law, regulation, or directive. Is there any law, regulation, or directive under which EPA would have authority to reverse FDA regulatory action resulting from such a finding? If so, would you please identify any such law, regulation, or directive.

Thank you in advance.

Very truly yours,

Gerald Steel
Attorney for OWOC & WASW

A-9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF THE
REGIONAL
ADMINISTRATOR

APR 07 2011

Dr. Bill Osmunson, DDS, MPH, President
Washington Action for Safe Water
1418 – 112th Ave NE #200
Bellevue, Washington 98004

Dear Dr. Osmunson:

I received your letter dated March 6, 2011, in which you outline Washington Action for Safe Water efforts concerning the fluoridation of public waters in Washington State to prevent dental caries. I hope the information below helps clarify EPA's role in the regulation of fluoride under the Safe Drinking Water Act (SDWA).

Under SDWA, EPA's role in drinking water regulation is to set standards that define the maximum allowable concentrations of contaminants in order to prevent adverse health effects. EPA does not provide recommendations for the addition of any substance (including fluoride) to drinking water for preventive health care purposes and is prohibited by SDWA from setting such requirements. Congress originally passed the SDWA in 1974 to protect public health by regulating the nation's public drinking water supply. SDWA authorizes the EPA to set national health-based standards for drinking water to protect against both naturally occurring and man-made contaminants that may be found in drinking water and requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. These non-enforceable health goals, based solely on possible health risks and exposure over a lifetime with an adequate margin of safety, are called maximum contaminant level goals (MCLGs). The current MCLG for fluoride is 4.0 mg/L or 4.0 ppm. EPA set this level of protection to meet the current public health goal for protection against increased risk of crippling skeletal fluorosis, a condition characterized by pain and tenderness of the major joints.

To achieve the MCLG for fluoride, the EPA has also set an enforceable regulation, called a maximum contaminant level (MCL), which is equal to the public health goal at 4.0 mg/L or 4.0 ppm. EPA announced in January that the agency is initiating review of the maximum amount of fluoride allowed in drinking water to determine whether it needs to be lowered in light of new EPA assessments of fluoride health effects and exposure. The new assessments conclude that sources of fluoride exposure have increased over the years because of increased access to fluoridated drinking water, foods and beverages processed with fluoridated water and consumer dental products such as fluoride toothpaste and mouth rinse.

EPA has also set a non-enforceable secondary maximum contaminant level (SMCL) for fluoride that recommends levels be kept below 2 mg/L to protect children from the tooth discoloration and/or pitting that can result from excess fluoride exposures. Secondary standards are recommended levels but EPA does not require water systems to comply. However, any community water system that exceeds the fluoride SMCL must notify customers of this exceedance and must include specific language prescribed by EPA regarding the possibility of dental fluorosis.

A-10

Neither the MCL nor SMCL for fluoride should be confused with the Department of Health and Human Services (HHS) new proposed recommendation of 0.7 mg/L for inclusion of fluoride in drinking water to promote public health. EPA's MCL is an enforceable level set to protect against risks from exposure to excess fluoride. The HHS recommended optimal level is set to promote public health benefits of fluoride for preventing tooth decay while minimizing the chance for dental fluorosis. HHS' proposed recommendation of 0.7 mg/L replaces the current recommended range of 0.7 to 1.2 milligrams. This updated recommendation is based on recent EPA and HHS scientific assessments to balance the benefits of preventing tooth decay while limiting any unwanted health effects.

In the state of Washington, the decision to fluoridate a water supply is made at the local level, e.g., local board of health, city council or mayors. When a community decides to fluoridate to promote oral health, the Washington's State Board of Health (SBOH) does have regulations that set the optimal range of fluoride that can be added to a public water system at 0.8 to 1.2 parts per million. Washington's levels were adopted at a slightly higher range because of the assumption at that time that people who live in cooler climates drink less water; and therefore, would receive less fluoride in their diet. It is my understanding that in response to the proposed changes by HHS, the SBOH is considering revising its regulations. Washington State does not mandate that systems fluoridate. However, if a community decides to fluoridate, the water system must follow the SBOH regulations on optimal levels and operational requirements that are overseen by the Washington State Department of Health, Office of Drinking Water as well as meeting EPA's enforceable MCL.

I hope that this helps to clarify EPA's role with respect to the regulation of fluoride in drinking water. If you need further clarification, please contact Michael A. Bussell, at (206) 553-4198, our Director for the Office of Water and Watershed and oversees the Drinking Water Unit for Region 10.

Sincerely

Dennis J. McLerran
Regional Administrator

cc: Ms. Denise Clifford
Washington Department of Health

Mr. Craig McLauglin
Washington's State Board of Health

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF
WATER AND
WATERSHEDS

NOV 17 2011

Mr. Gerald Steel, PE
Attorney-at-Law
7303 Young Road NW
Olympia, Washington 98502

Dear Mr. Steel:

I am responding to your letter dated November 7, 2011, on behalf of Dennis J. McLerran, Regional Administrator, U S. Environmental Protection Agency (EPA). In your communication you have asked the EPA to send you a letter that answers the question "Are [Washington Administrative Code] WAC 246-290-220(3) and 246-290-460 part of implementation of requirements of the Federal Safe Drinking Water Act in Washington State, or are they unrelated to the requirements of the Federal Safe Drinking Water Act in Washington State?"

A concise answer to your question is that the provisions at WAC 246-290-220(3) and 246-290-460 are not related to the requirements of the Federal Safe Drinking Water Act in Washington State. An explanation as to why this is the case follows.

The requirements for a State drinking water primacy program are spelled out in Section 1413 of the Federal Safe Drinking Water Act (SDWA) (42 U.S.C. § 300g-2). Section 1413(a) specifies that a State has primary enforcement responsibility (primacy) for public water systems during any period for which the EPA Administrator determines that such State:

(1) has adopted drinking water regulations that are no less stringent than the national primary drinking water regulations i.e., the regulations promulgated at 40 CFR Part 141 (see http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?tpl=/ecfrbrowse/Title40/40tab_02.tpl);

(2) has adopted and is implementing adequate procedures for the enforcement of such State regulations as the Administrator may require by regulation;

(3) will keep such records and make such reports with respect to its activities as the Administrator may require by regulation;

(4) if it permits variances and/or exemptions from the requirements of its drinking water regulations, permits such variances and exemptions under conditions and in a manner which is not less stringent than the conditions under, and the manner in which variances and exemptions may be granted under SDWA sections 1415 and 1416;

(5) has adopted and can implement an adequate plan for the provision of safe drinking water under emergency circumstances; and

(6) has adopted authority for administrative penalties, unless the constitution of the State prohibits the adoption of such authority.

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The EPA's role in SDWA section 1413(b) requires the Administrator to promulgate regulations that establish how the States may apply for primacy, how the Administrator will make primacy determinations and the manner in which the Administrator may determine that the primacy agency is no longer meeting the primacy requirements. These primacy implementing regulations can be found at 40 CFR 142.10 – 40 CFR 142.12. (See enclosure and/or website provided above.) 40 CFR Part 142.10 describes the requirements of a State primacy program. 40 CFR Part 142.11 describes the documents a State must submit to the EPA for an initial determination of primacy. 40 CFR 142.12 describes the contents of a State request for approval of a State's revised primacy program. This must take place whenever the EPA adopts a new or revised drinking water rule. As per 40 CFR 142.12(c) a State must submit for EPA approval a copy of their regulations and a document we refer to as a crosswalk. The crosswalk is a side-by-side comparison of the new or revised Federal requirements in 40 CFR Parts 141 and 142 and the corresponding State authorities, including citations to the specific statutes and administrative regulations (see enclosed example of a crosswalk page). EPA will only make a determination that a State's revised drinking water primacy program can be approved if the State's regulations are as stringent as the Federal regulations and the State continues to maintain all required authorities as per SDWA Section 1413.

WAC 246-290-220(3) requires treatment chemicals with the exception of commercially retailed hypochlorite compounds added to water intended for potable use to comply with ANSI/NSF Standard 60 and also specifies that the maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice. The Department of Health (DOH), which is the State of Washington's drinking water primacy agency has never submitted WAC 246-290-220(3) to the EPA for approval as there is no analogous provision in the National Primary Drinking Water Regulations at 40 CFR Part 141, and neither the other statutory provisions mentioned above, nor the primacy implementing provisions at 40 CFR Part 142 require that language, such as is found in WAC 246-290-220(3), be part of a State primacy program.

WAC 246-290-460 addresses fluoridation practices, should a community choose to provide fluoridation. DOH has never submitted WAC 246-290-460 to the EPA for approval as there are no analogous provisions in the National Primary Drinking Water Regulations at 40 CFR Part 141, and neither the other statutory provisions mentioned above, nor the primacy implementing provisions at 40 CFR Part 142 require that a State primacy program regulate fluoridation practices.

For the reasons stated in the above paragraphs, I can assert that that the provisions at WAC 246-290-220(3) and 246-290-460 were not required to be submitted by the State or approved by the EPA and these provisions are not related to the requirements of the Federal Safe Drinking Water Act.

I hope this response answers your questions satisfactorily. If you have additional questions, please contact Marie Jennings, our Manager for the Drinking Water Unit at (260) 553-1893.

Sincerely,

Michael A. Bussell, Director
Office of Water & Watersheds

A-13

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OCT 10 2012

OFFICE OF
WATER AND WATERSHEDS

Mr. Gerald Steel, PE
Attorney at Law
7303 Young Road NW
Olympia, Washington 98502

Dear Mr. Steel:

Your letter dated August 3, 2012, has been forwarded to the Office of Water and Watersheds for a response because my office is responsible for the implementation of the drinking water regulations. In your letter, you reiterate certain provisions of the Safe Drinking Water Act as we described them in letters from our office dated April 7, 2011, and November 17, 2011.

You go on to refer to various sections of the Washington Administrative Code, specifically WAC 246-290-220(3), which addresses treatment chemicals added to drinking water and WAC 246-290-460, which addresses drinking water fluoridation practices.

As noted in the U.S. Environmental Protection Agency (EPA) letter of November 17, 2011, neither WAC 246-290-220(3) nor WAC 246-290-460 are related to the requirements of the Federal Safe Drinking Water Act in Washington State.

You ask if there is any law, regulation, or directive giving the EPA authority to prevent the Food and Drug Administration and/or Health and Human Services from exercising their drug authority to make a finding that fluoride products added to drinking water are drugs and if there is any law, regulation or directive giving the EPA authority to reverse any FDA regulatory action resulting from such a finding. The answer to both of these questions is no. The EPA has no authority to intervene in the actions of these agencies. If you have additional questions, please contact Fredianne Gray, our Regulatory Fluoride expert, at (206) 553-6387.

Sincerely

Daniel D. Opalski
Office of Water and Watersheds

A-14

No. 43252-8-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN, Appellants, v. CITY OF PORT ANGELES, and CITY OF FORKS, Respondents.	DECLARATION OF BILL OSMUNSON DDS MPH

COMES Now Bill Osmunson DDS MPH, and declares as follows:

1) I am over the age of 21 and competent to testify. I make this declaration based on my own knowledge and belief.

2) I got my Doctor of Dental Surgery in 1977. For my first 25 years of private practice and without personally reviewing the science, I promoted fluoridation of public water. Over the last 8 years, I have dedicated over 10,000 hours on the science

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG RD. NW
OLYMPIA WA 98502
Tel/fax (360) 867-1166

A-15

surrounding the practice of fluoride treatments, testing fluoride content of foods, educating dentists and the public on the lack of FDA CDER approval of fluoride, lack of benefit of ingesting fluoride, and the serious risks from excess fluoride ingestion. I am the current president of Washington Action for Safe Water ("WASW"), a Washington State non-profit corporation.

3) I petitioned the state Board of Health and the state Board of Pharmacy for rule-making regarding fluoride and fluoridation. Amended Appellants' Clerk's Papers ("ACP") 124 is the response from the state Board of Health to my petition for Rule Making.

4) ACP 46 is the response from the state Board of Pharmacy to my petition.

5) Appendix A-17 hereto is a true and correct copy of a page from the PowerPoint presentation I gave to the state Board of Pharmacy that frames the requests that are answered in the Board's decision provided in ACP 46.

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my knowledge and belief.

Signed the 1st day of December, 2012 at Redmond WA.

Bill Osmunson DDS MPH

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG RD. NW
OLYMPIA WA 98502
Tel/fax (360) 867-1166

REQUESTS to the Board of Pharmacy

#1

Designate fluoridation substances as Poison

RCW 69.38.010

#2

Require ingested fluoridation substances for mitigation of human disease be dispensed only as a Legend Drug

RCW 69.38.020 and RCW 69.41

A-17

No. 43252-8-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN, Appellants, v. CITY OF PORT ANGELES, and CITY OF FORKS, Respondents.	FOURTH DECLARATION OF ELOISE KAILIN M.D.

COMES Now Eloise Kailin M.D., and declares as follows:

1) I am over the age of 21 and competent to testify. I make this declaration based on my own knowledge and belief.

2) I concur that by February 6, 2012, neither I nor Gerald Steel had received a written statement from U.S. HHS that identifies the classification of water fluoridation

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG RD. NW
OLYMPIA WA 98502
Tel/fax (360) 867-1166

products and the component of FDA that will regulate these products. *See* Declaration of Gerald Steel, Para. 7.

3) I concur that neither I nor Gerald Steel have received a request or notice of modification from U.S. HHS pursuant to 21 U.S.C. 360bbb-2(c) and we have not provided written consent to any modification from the final determination by the Secretary of HHS that fluoridation products are drugs and prescription drugs regulated by CDER. *See* Declaration of Gerald Steel, Para. 11.

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my knowledge and belief.

Signed the 1ST day of December, 2012 at Sequim WA.

Eloise Kailin M.D.

Eloise Kailin M.D.

GERALD STEEL, PE
ATTORNEY-AT-LAW
7303 YOUNG RD. NW
OLYMPIA WA 98502
Tel/fax (360) 867-1166

APPENDIX B

INTERESTS OF AMICI CURIAE

APPENDIX B

INTERESTS OF AMICI CURIAE

Our Water-Our Choice!

Our Water-Our Choice! ("OWOC!") is a Continuing Political Committee registered with the Washington Public Disclosure Commission. Its address is 316 Power Plant Rd., Port Angeles WA 98369. Mike Libera of Port Angeles is listed as the Campaign Manager and Cindy Paulin is listed as the Treasurer. Our Water-Our Choice! was initially formed in 2006 and was the sponsor of the initiative petition that is attached hereto as Appendix B-1 and B-2. The intent of the ordinance proposed in the initiative petition was to prohibit medication of people through additives to public drinking water supplies. Appendix B-1 hereto. While the petition was not limited to fluoridation medication, and was not limited to the Port Angeles municipal water supply, it considered fluoride used for fluoridation as a prohibited medication in the Port Angeles municipal water supply.

OWOC! believes that water fluoridation is unsafe and believes that medications and drugs should not be allowed to be added to public water supplies without compliance with laws and regulations that govern manufacture and distribution of drugs. In a 5-4 Decision, the state Supreme Court ruled that the OWOC! sponsored initiative was administrative and therefore beyond the scope of the local initiative power. *City of Port Angeles v. Our Water-Our Choice!*, 170 Wn.2d 1, 5-15, 239 P.3d 589, (2010). The *Our Water-Our Choice*! Court did not recognize that the initiative applied to all medications and all public water supplies serving the City and instead characterized the initiative solely as trying to repeal the City's fluoridation program. *Id.* at 5. The *Our Water-Our Choice!* Court also refused to rule on whether fluoride used to make fluoridated water is a medicine (drug). *Id.* at 12, note 6.

OWOC! has continued to research whether fluoride used to make fluoridated water is a drug and has researched the roles of the FDA and HHS and the role of EPA regarding the regulation of fluoride additives in public drinking water. OWOC! has concluded that fluoridation products used to make fluoridated public drinking water are drugs under the authority of HHS and FDA and the state Board of Pharmacy.

Washington Action for Safe Water

Washington Action for Safe Water ("WASW") is a non-profit corporation working to improve the quality of water in Washington State. As its policy, WASW believes that

communities should not add substances to public water supplies for the medication of people. And if police powers are required to medicate people for the prevention of disease, the drugs used must comply with the Food, Drug, and Cosmetic Act and be approved by the Food and Drug Administration Center for Drug Evaluation and Research, manufactured as required by the FD&C Act in an approved licensed drug manufacturing facility and dispensed as required by state laws and regulations under the supervision of a licensed health care professional.

APPENDIX C

APPELLANTS' CLERK'S PAPERS
PAGE 46

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

June 4, 2009

Bill Osmunson DDS, MPH
Aesthetic Dentistry of Bellevue
1418 112th Avenue NE, Suite 200
Bellevue, Washington 98004

Dear Dr. Osmunson:

This letter is in response to your request at the May 7, 2009 meeting of the Washington Board of Pharmacy for a response to your question about designating fluoride as a poison under chapter 69.38 RCW. RCW 69.38.020 states that "[a]ll substances regulated under chapters 15.58, 17.21, 69.04, and 69.50, and chapter 69.45 RCW are exempt from the provisions [of chapter 69.38 RCW]. Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a "legend drug" as drugs "which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only." In WAC 246-883-020 (2), the Board specified that "legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*." Enclosed are copies of pages 169, 342, and 690 of the 2002 edition of the *Drug Topics Red Book*. Page 169 is the key to the products requiring prescription (legend drugs) and page 342 contains the fluoride products. Page 690 contains the listing of over-the-counter fluoride products, primarily toothpaste containing fluoride.

While RCW 69.41.010 restricts the dispensing of prescription drugs to practitioners, the legislature has authorized water districts to fluoridate their water supplies in RCW 57.08.012. This authority was recognized by the Washington Supreme Court in *Parkland Light & Water Company v. Tacoma-Pierce County Board of Health, et al.*, 151 Wn.2d 428 (2004). By adopting a specific statute on the fluoridation of water supplies, the legislature has superseded the more general statutes in the legend drug act requiring a practitioner to dispense fluoride. *Tunstall v. Bergeson*, 141 Wn.2d 201, 211 (2000).

For the above-stated reasons, the Board of Pharmacy will not be considering your request to designate fluoride as a poison under chapter 69.38 RCW.

Sincerely,

Susan Teil Boyer

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